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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------------|------------------|
| 10/680,705 | 10/07/2003 | Gregory B. Altshuler | 105090-194 | 2638 |
| 21125 7590 04/03/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | EXAMINER JOHNSON III, HENRY M | |
| | | | ART UNIT 3739 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/03/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/680,705 | Applicant(s) ALTSHULER ET AL. | |
| | Examiner Henry M. Johnson, III | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 20-29, 32-35, 37-61 and 69-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 20-29, 32-35, 37-61 and 69-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments with respect to claims have been considered but are not persuasive regarding Altshuler et al. and the controlling of the flux and moot in view of Dumoulin-White et al. with regard to multiple sources.

Altshuler et al. teaches controlling the source based on temperature feedback. Regardless of the control methodology, the flux is controlled.

Dumoulin-White et al. teaches two laser sources, each independently controlled by feedback from the target tissue, providing the ability to use either of both sources for controlling the temperature of the tissue.

Claim Objections

Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. No additional method step is provided in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 29 recites the limitation "the first portion" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner believes this should be dependent on claim 26.

Claim 49 recites the limitation "said first and second portions" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 20-25, 32, 33, 35, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,273,884 to Altshuler et al. Altshuler et al. disclose an apparatus and method for irradiating tissue and providing pre-heating and/or pre-cooling to the tissue. Biostimulation within tissue may result from virtually any irradiating of electromagnetic energy. Altshuler et al. teach methods and apparatus for dermatology treatment using radiation, preheating of the treatment volume, precooling, cooling during (simultaneous) treatment and post-treatment (sequential) cooling of the epidermis above the treatment volume and various beam focusing techniques (abstract). Peltier elements (Fig. 2, # 56) are disclosed on either side of a moveable radiation source (Fig. 2, # 50) that provide the heating and cooling from a source separate from the radiation source. The Peltier units contact specific areas of tissue that are interpreted as selected first and second portions. The radiation source is disclosed as either coherent or incoherent with the coherent sources including a variety of lasers including diode lasers (Col. 6, lines 24-28). The lasers inherently have narrow bandwidths. Altshuler et al.

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teaches wavelengths of from 600-1200 nanometers (Col. 11, line 36). Altshuler et al. teaches the heating enhances the radiation effect (Col. 1, lines 16-19). This is interpreted as increasing the efficacy of the biostimulation. Altshuler et al. teaches heating in a range of 40 to 60 °C and cooling in a range from -30 to 20 °C. It is inherent that cooling is used to protect a surface layer of tissue while treating a level below the surface. The device may include a lens or other suitable focusing or non-focusing optical transmission component (Col. 7, lines 59-61). The delivery unit is coupled to the radiation source by a fiber optic cable (Fig. 2, # 32). The device also includes a thermocouple or other suitable temperature sensor mounted close to surface. The temperature sensor connects to controls and may be utilized to control epidermal temperatures or for other suitable purposes (Col. 15, lines 5-8) by control of the optical source (Col. 6, lines 56-58). Control of the source inherently controls the flux of the energy to the target tissue. Whether the control is of the pulse parameters, time or the power to the source, the flux, intensity and fluence are inherently controlled in the process.

Regarding claim 33, Altshuler et al. teaches the use of flowing water, and flowing gas or spray at a desired temperature may be utilized for thermal components (Col. 8, lines 15-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent Application Publication US 2001/0023363 to Harth et al. Altshuler et al. are discussed above, but do not teach wavelengths below 600 nanometers. A skilled artisan would select the wavelength appropriate for the desired effect. Harth et al. teach a device for treatment of acne with radiation with a wavelength of 405 to 440 nanometers to induce the porphyrins to produce oxygen. The process is biostimulation. Treatment times are disclosed as 15, 30 and 60 minutes. A fan is disclosed that serves to cool and remove excess heat (control temperature) from the treated skin area (paragraph 0058), the fan being an independent source. The intensity on the skin area is disclosed in the range of 10 mW/cm² to 500 mW/cm² (paragraph 0030) and the beam is diverging at a small angle and creates an oval shaped illumination area of typical size 20X10 cm (paragraph 0071) which yields an area of 200 cm². The intensity over a 15 minute interval yields a fluence of 9-450 J/cm².

Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent 6,413,267 to Dumoulin-White et al. Altshuler et al. are discussed above, but do not teach multiple sources of radiation. Dumoulin-White et al. teach an apparatus and methods for biostimulation using two wavelengths of laser light (Col. 1, lines 35-55) and disclose how the wavelength impacts the penetration depth in tissue. Dumoulin-White et al. disclose a first laser with a wavelength from 450 to 749 nanometers and a second laser with the wavelength from

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750 to 1000 nanometers each separately controlled by a closed loop with feedback from the target tissue (Fig. 1). Optics are disclosed for delivery of the energy to the tissue (Fig. 1). The invention is disclosed as suitable for controlling thermal laser applications, implying the feedback is temperature (Col. 7, lines 22-25). The method of use, irradiating tissue with a first radiation and irradiating tissue with a second radiation and modulating the output, is implicit in the device structure. It would have been obvious to one skilled in the art to use the dual laser sources as taught by Dumoulin-White et al. in the invention of Altshuler et al. to provide the treatment and penetration as discussed by Dumoulin-White et al.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent 6387089 to Kreindel et al. Altshuler et al. are discussed above, but do not teach a cream for adjusting temperature. Kreindel et al. disclose an apparatus and method for wrinkle smoothing using radiation with a range of 600-1600 nanometers (Col. 2, line 36) and cooling the treated area with ice, a gel or a crystal in contact with the surface (abstract). Ice teaches vaporization and gel is interpreted as a cream. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use cooling methods as taught by Kreindel et al. in the invention of Altshuler et al. as such evaporation cooling is common and well known in the art.

Claims 39-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. in view of U.S. Patent 6,413,267 to Dumoulin-White et al. All have been previously discussed. It would have been obvious to one skilled in the art to use the dual laser sources as taught by Dumoulin-White et al. in the invention of Altshuler et al. to provide the treatment and penetration as discussed by Dumoulin-White et al.

Regarding claims 55, 57 and 59-61, optics for delivery of laser energy to a target are well known in the art and a skilled artisan would select from the various fibers, lenses, splitters,

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etc. to provide the desired treatment pattern. It is also noted that no unexpected result or benefit is disclosed using a unique delivery system.

Claims 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,273,884 to Altshuler et al. in view of U.S. Patent 6,413,267 to Dumoulin-White et al. as applied to claim 48 above and further in view of U.S. Patent Application Publication US 2001/0023363 to Harth et al. All have been previously discussed. The use of light arrays of LEDs and laser diodes is pervasive in the art as evidenced by the LED arrays taught by Harth et al. It would have been obvious to one skilled in the art to use semiconductor arrays as taught by Harth et al. in the invention of Altshuler et al. in view of Dumoulin-White et al. as alternative equivalent sources for the light energy for the treatment. A skilled artisan would most certainly be motivated to look to such arrays to take advantage of the size and power benefits of the semiconductor sources.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

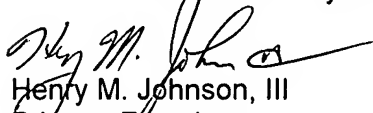
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
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